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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/545,191	08/10/2005	Lothar Gobel	KCX-1261-PCT-US (64357872)	1365
7590 Dority & Manning, P.A. P.O. BOX 1449 Greenville, SC 29602			EXAMINER STIGELL, THEODORE J	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 02/02/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/545,191	Applicant(s) GOBEL, LOTHAR	
	Examiner THEODORE J. STIGELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☒ Claim(s) 6 and 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/23/2009 has been entered.

Oath/Declaration

The oath submitted on 12/11/2008 is acknowledged and accepted.

Specification

The amendments to the specification filed on 12/11/2008 are acknowledged and accepted.

Drawings

The drawings were received on 12/11/2008. These drawings are accepted.

Claim Objections

Claims 6 and 8 are objected to because of the following informalities: There is no antecedent basis for "the end" or "the catheter shaft". Appropriate correction is required.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-11, 13-19, 21-24, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Williamson (5,545,179). Williamson discloses a device (20) capable of tamponade of body cavities and mechanical anchoring of catheters comprising a flexible tube segment (36, 39, 40) having an inner wall and an outer wall that surround an interior space wherein said tube segment is inflatable to assume a generally torus geometry with said inner wall defining an internal area, and the internal area is configured without through-passing support bodies so that a displacement of tube wall material between said inner wall and said outer wall of said tube segment is possible as inflation proceeds, wherein said tube segment further comprises two ends (not numbered), which are fastened to a same closing element (25), configured so that a torus geometry is striven for as said inflatable tube segment is inflated and said closing element is a pipe nipple and said two ends of said tube segment are joined together fluid-tightly, wherein the outer wall is thin and expandable, wherein the tube is made of at least polyurethane, wherein the tube can be formed by invagination, wherein the tube is of uniform thickness and is capable of receiving substances, further comprising a channel (34) to inflate the tube segment, and further comprising a collar shaped abutment or shield (27).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson (5,545,179). Williamson discloses all of the limitations recited in the independent claim but fails to teach using a transparent material or an inner wall with a greater thickness. These limitations are deemed to be design considerations as the applicant has not shown that they provide any advantage or solve any problem.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson (5,545,179) in view of Buckholtz et al. (5,409,006). Williamson discloses all of the limitations recited in the independent claim but fails to disclose a pressure sensor. Buckholtz discloses that pressure sensors are beneficial in medical access devices. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the

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invention to modify the device of Williamson with the pressure sensor of Buckholtz to make a securement device that could make sure the appropriate inflation pressure was present.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson (5,545,179) in view of Taylor (5,935,107). Williamson discloses a medical access device that includes all of the limitations recited in the independent claim but fails to explicitly teach to include an electrode. Taylor discloses that is well known in the medical access device art to include an electrode. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Williamson with the electrode of Taylor.

Response to Arguments

Applicant's arguments with respect to claims 1-26 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763